

Atty Dkt. No.: SIER-022CON
USSN: 10/826,466

REMARKS***Formal Matters***

Claims 1-45, 47 and 50-52 are withdrawn from consideration. Claims 46, 48 and 49 are pending and under examination.

Claim 46 has been amended for clarity. Claims 53 to 61 have been added. Support for new claims 53-56 can be found in the specification in paragraph [91]. Support for new claims 57 and 58 can be found in the specification in paragraphs [92], [93] and original claims 8 and 9. Support for new claims 59-61 can be found in the specification in paragraphs [77] and [91].

The second paragraph under *Example 1* of the *Experimental* section on page 34 of the specification has been amended to include the sequence identification number as requested by the Examiner.

As no new matter is added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Priority

The Examiner asserts that the Applicant's claim for the benefit of a prior-filed application was not provided in the first line of the specification as required.

However, the Applicants note that a preliminary amendment was filed with the subject application which amended the first paragraph to include this information (please see Appendix A).

The Applicants respectfully request entry of this previously filed amendment which places the claim for the benefit of a prior-filed application in compliance with 37 CFR 1.78(a).

Specification

The Examiner states that the sequence listed on page 34 of the specification lacks a SEQ ID NO designation.

In response, the Applicants have amended the specification (as shown above) to include the SEQ ID NO designation for this sequence.

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Claim Objections

The Examiner objects to Claim 46 for ambiguity regarding the nature of the "agent" in the claim.

In response, the Applicants have amended Claim 46 to delete the word "that", thereby clarifying the nature of the term "agent" in the claim. As such, withdrawal of this objection is respectfully requested.

Double Patenting

The Examiner has provisionally rejected Claims 46, 48 and 49 on the grounds of obviousness type double patenting over Claims 1-4 and 6-16 of copending and commonly owned Application No. 11/198,933.

In response, the Applicants file herewith a terminal disclaimer in compliance with 37 CFR 1.321(c). As such, this rejection may be withdrawn.

Claim Rejections – 35 USC § 112

The Examiner has rejected Claims 46, 48 and 49 under 35 USC § 112, first paragraph for failing to comply with the enablement requirement.

In making this rejection, the Examiner states the following:

While demonstrating that the GC-Box 5 sequence is present in their hTERT promoter expression system that when modified or deleted results in increased hTERT transcriptional activity in MRC5 cells, the applicant has not provided enough information describing the manner by which the repressive element functions to encompass the broad nature of the claimed invention and therefore to enable the instant invention.

The Examiner asserts that one of skill in the art would have to engage in undue experimentation and discovery to practice the claimed invention in view of the teachings of the specification. The Examiner goes on to assert that one of skill in the art would have to: 1) determine how an agent interacts with the GC-Box (e.g., directly or through interaction with GC-Box binding factors/co-factors); 2) determine how to treat cells with an agent having the claimed expression system; 3) determine if the GC-Box 5 element

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is functional in the TERT promoter used in the claimed expression system; 4) determine whether the effects of the agent are through GC-Box 5 associated factors or other regions of the TERT promoter; and 5) determine the types of cells that can be used for the claimed screen.

With regard to the level of experimentation necessary for an artisan to make and use the invention, MPEP § 2164.06 states:

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Teletronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046 (1989).

As is clear from this section, it is the level of guidance provided by the specification, not the level or amount of experimentation required, that is to be assessed when determining whether the specification enables the claims. As is discussed below, the Applicants submit that the claims are fully enabled by the specification.

The Applicants submit, and the Examiner acknowledges, that the specification clearly demonstrates that the GC-Box5 sequence in the TERT promoter has a repressive effect on TERT promoter activity in certain cells (e.g., MRC5 cells). Specifically, mutation/deletion of all or part of the GC-Box5 sequence results in increased transcription from the TERT promoter (see Examples section). Therefore, the Applicants have demonstrated that the GC-Box5 sequence represses TERT promoter transcription in certain cells. The Applicants then provide guidance as to how one of skill in the art can use this information for a variety of practical uses, including setting up a

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screen for identifying agents that inhibit repression from the GC-Box5 region (see especially page 32, paragraph [91] to page 34, paragraph [94]).

The specific reasons given for the Examiner's lack-of-enablement conclusion (see items 1-5, listed above) fall into two general categories. The first of these are issues that relate to the level of skill in the art of setting up and executing a screening assay (items 2, 3 and 5). The second is related to uncertainty regarding the specific mechanism through which the GC-Box5 inhibits TERT transcription and how an agent being screened in the claimed assays might function to inhibit the activity of this repressor element (items 1 and 4).

With regard to items 1, 3 and 5, the Applicants submit that one of skill in the art of performing screening assays, in which the skill level is very high, would readily be able to make and use the claimed invention in view of the specification. The issues raised by the Examiner are those faced routinely by those of skill in the art and are related to setting up standard control experiments for an assay. For example, determining which cells to use in the screen is a mere matter of ensuring that the coding sequence of the expression system (i.e., one having a GC-Box5 element) is repressed when present in a cell. If it is not repressed, meaning that the coding sequence is expressed constitutively in the cell, then the cell is not appropriate for the screen. This is clearly described in the specification (e.g., see paragraph [91]).

Furthermore, this type of analysis is routinely done in the agent-screening art, as any type of agent screen must be set up in such a way as to provide accurate and specific data or be useless for its intended purpose. It is likewise a routine endeavour for one of skill in the art, once made aware of the repressive effect of the GC-Box5 element in the TERT promoter, to determine whether a GC-Box 5 containing expression system will function as expected (e.g., by testing it in MCR5 cells). None of this type of analysis is undue to one of skill in the art.

In addition, contacting an agent with an expression system of the invention is also an element that is routine in the art. One of skill having agents to screen and a screening system as claimed (and disclosed in the specification) would not find it undue to determine how to contact the agent to the expression system. Again, this type of

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analysis and experimentation is engaged in routinely in the art and is therefore not undue.

With regard to items 1 and 4, the Examiner is asserting that because the mechanism of repression through the GC-Box5 element is not known (and thus not disclosed in the specification), that one of skill in the art would not be able to determine whether an agent is having a direct or indirect effect on repression of the expression system through this particular element.

In response, the Applicants submit the claimed invention is not drawn to identifying the mechanism of action of an agent that inhibits repression through a GC-Box5 element. Rather, the claimed invention is drawn to identifying agents that, regardless of the specific mechanism of action, inhibit GC-Box5-mediated repression of the TERT promoter. In other words, if an agent reverses the repressive effects of the GC-Box5 repressor element in the expression system, then it meets the criteria as a GC-Box5 repressor inhibitor. The mechanism of action is of no consequence.

Therefore, the Applicants submit that one of skill in the art can make and use the claimed invention without undue experimentation. As such, withdrawal of this rejection is respectfully requested.

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CONCLUSION

In view of the amendments and remarks above, the Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number SIER-022CON.


Respectfully submitted,
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